

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

INNOVATIVE THERAPIES, INC.,

Plaintiff,

v.

KINETIC CONCEPTS, INC., KCI  
LICENSING, INC. and KCI USA, INC.

Defendants.

C.A. No. 1:07-cv-589-SLR

**DECLARATION OF RICHARD VOGEL**

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1. I am a co-founder and the Chief Executive Officer of Innovative Therapies, Inc. ("ITI"), which was conceived in 2004 and incorporated in the state of Delaware in July of 2006.

2. I was an officer of Kinetic Concepts, Inc. ("KCI") for approximately four years from 1996 to 2000, during which time I served as the General Manager of New Technologies, a member of the Executive Committee, and a corporate Vice President.

3. As a former member of KCI's Executive Committee, I am familiar with the breadth of knowledge that a Committee member has regarding corporate affairs. An Executive Committee member, such as Michael Burke, would be aware of the corporate policy regarding enforcement of the company's patent rights.

4. I believed that as an Executive Committee member and Senior Vice President of the company, Michael Burke would be able to provide a realistic assessment of KCI's mind-set regarding enforcement of its patents against competitive products, including negative pressure, foam-based devices.

5. I believed that given his level in the KCI organization, Michael Burke would be in a position to introduce Innovative Therapies to the right person in the event KCI would be

interested in discussing a business relationship.

6. As a former member of KCI's Executive Committee, I am familiar with the litigation decision-making process and tactics of KCI. I assisted in forming litigation strategy relating to the New Technologies Division of KCI. I previously served as a corporate representative witness on behalf of KCI during a mediation.

7. I recognized that there was a considerable segment of wound care patients that could not afford the significant costs associated with use of KCI's V.A.C. and thus could not benefit from negative pressure wound therapy to reduce their healing time and increase their level of comfort while healing.

8. I also recognized that hundreds of thousands of patients with chronic wounds would benefit from the introduction of an affordable and effective negative pressure wound therapy device. By having such a product on the market, many of these patients will be able to avoid amputations resulting from infected wounds that could have been avoided if the patients were able to afford negative pressure wound therapy.

9. Dr. Paul Svedman is a plastic and reconstructive surgeon, professor of medicine, and prolific inventor. Since 1976, Dr. Svedman has been a pioneer in the field of wound therapy, and a variety of modern day wound treatment techniques are directly attributable to his work. Dr. Svedman's work resulted in a number of issued and pending patents in Sweden and the United States, a host of publications in multiple medical journals, and numerous requests for lectures explaining his innovative system to others in the medical community throughout the world.

10. After locating the negative pressure wound therapy work and prior art of Dr. Paul Svedman, I approached Dr. Svedman and several other people regarding the possibility of founding a company to research, develop, and produce innovative therapies in the field of patient wound care.

11. ITI was created to research, develop, and produce innovative therapies in the field of patient wound care.

12. Based on the public need, and with the expertise of Dr. Svedman, ITI endeavored to create an affordable negative pressure wound therapy device based upon Dr. Svedman's pioneering work in the field of wound treatment in the late 1970s and early 1980s.

13. In 2007, ITI successfully developed its first negative pressure wound therapy device, combining suction and irrigation with a polyurethane foam dressing. The device was named the Svedman Wound Treatment System ("Svedman<sup>TM</sup> system").

14. The cost of the Svedman is significantly lower than that of other competitive products on the market, particularly the KCI V.A.C. Therefore, patients with serious wounds who were previously unable to afford effective wound healing assistance can now benefit from negative pressure wound therapy.

15. ITI invested significant time and money in developing the Svedman. In August and September 2007, ITI conducted clinical evaluations of the Svedman with five patients. The chronic wounds of all five patients successfully healed after treatment with the Svedman. These evaluations clearly demonstrated both the safety and efficacy of the Svedman in the treatment of chronic wounds.

16. ITI also submitted two 510(k)s to the FDA for approval of two embodiments and uses of the Svedman as a medical device. The FDA cleared (or approved) both submissions.

17. One 510(k) submission was entitled "ANTLIA I Wound Irrigation System." ANTLIA I was directed to a device utilizing a combination of negative pressure and irrigation for wound drainage. It identified KCI's V.A.C. Instill as a predicate device and stated that the ANTLIA I "has essentially the same technological characteristics as the previously cleared predicate device."

18. The other 510(k) submission was entitled "ANTLIA II Suction Pump System." ANTLIA

It was directed to a device utilizing only negative pressure for wound drainage. It identified Medela's Invia Healing System and BlueSky's Medical Versatile 1 Wound Vacuum System as the predicate devices.

19. The efficacy of the Svedman is attributable to the fact that the device promotes wound healing by facilitating wound drainage through the combination of negative pressure and irrigation. I consider the Svedman to be superior to competitive products because it provides comparable performance in a simpler, more cost-effective package.

20. ITI made its first offer for sale of the Svedman on September 27, 2007.

21. The first Svedman was placed with a customer in the first week of October 2007.

22. Since the first placement, at least a dozen patients have utilized the Svedman and experienced successful results. In several cases, the Svedman provided successful healing outcomes where competitive products had previously failed.

23. While marketing the Svedman, ITI has approached dozens of potential customers. In nearly every case, the potential customers have asked whether KCI will sue ITI because the Svedman is a negative pressure, foam-based device.

24. ITI is not a resident of the State of North Carolina.

25. ITI is a Delaware corporation, with its principal place of business at 10948 Beaver Dam Road, Suite E, Hunt Valley, Maryland 21030.

26. ITI does not maintain a place of business in North Carolina.

27. ITI has no employees in North Carolina. All of the officers of ITI reside in Maryland.

28. ITI does not own any real property in North Carolina.

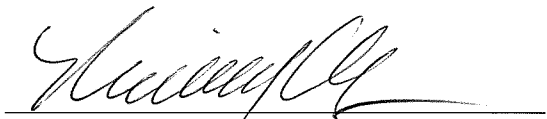
29. ITI does not own any tangible property in North Carolina.

30. ITI has had only one customer ever in the state of North Carolina, and currently no Svedman systems are placed at any site in North Carolina.

31. KCI effected service of Plaintiff's Complaint on ITI's corporate agent located in Delaware.

32. The facts set forth above are true and complete to the best of my knowledge and recollection.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 4th day of April, 2008.

  
Richard Vogel

**CERTIFICATE OF SERVICE**

I hereby certify that on April 4, 2008, a copy of the foregoing Declaration of Richard Vogel was served with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following

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In addition, the forgoing was also served via e-mail upon:

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